§§ 1320c–21, 1320c–22. Omitted

CODIFICATION

Sections 1320c–21 and 1320c–22 were omitted in the general revision of this part by Pub. L. 97–248, title I, § 143, Sept. 3, 1982, 96 Stat. 382.

Section 1320c–21, act Aug. 14, 1935, ch. 531, title XI, § 1172, as added Oct. 25, 1977, Pub. L. 95–142, § 5(k), 91 Stat. 1190; amended Aug. 13, 1981, Pub. L. 97–35, title XXI, §§ 2113(*l*), 2193(c)(7), 95 Stat. 795, 827, related to annual reports submitted to Congress by Secretary. See section 1320c–10 of this title.

Section 1320c–22, act Aug. 14, 1935, ch. 531, title XI, § 1173, as added Oct. 25, 1977, Pub. L. 95–142, § 5(*l*)(1), 91 Stat. 1191; amended Dec. 5, 1980, Pub. L. 96–499, title IX, § 923(e), 94 Stat. 2628, provided that medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands were includable in program under former Part B. See section 1320c–12 of this title.

PART C—ADMINISTRATIVE SIMPLIFICATION

§ 1320d. Definitions

For purposes of this part:

(1) Code set

The term ''code set'' means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(2) Health care clearinghouse

The term ''health care clearinghouse'' means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

(3) Health care provider

The term ''health care provider'' includes a provider of services (as defined in section 1395x(u) of this title), a provider of medical or other health services (as defined in section 1395x(s) of this title), and any other person furnishing health care services or supplies.

(4) Health information

The term ''health information'' means any information, whether oral or recorded in any form or medium, that—

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

(5) Health plan

The term ''health plan'' means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 300gg–91 of this title). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 300gg–91(a) of this title), but only if the plan—

(i) has 50 or more participants (as defined in section 1002(7) of title 29); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

(B) A health insurance issuer (as defined in section 300gg–91(b) of this title).

(C) A health maintenance organization (as defined in section 300gg–91(b) of this title).

(D) Parts[1] A, B, C, or D of the Medicare program under subchapter XVIII of this chapter.

(E) The medicaid program under subchapter XIX of this chapter.

(F) A Medicare supplemental policy (as defined in section 1395ss(g)(1) of this title).

(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10.

(J) The veterans health care program under chapter 17 of title 38.

(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5.

(6) Individually identifiable health information

The term ''individually identifiable health information'' means any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(7) Standard

The term ''standard'', when used with reference to a data element of health information or a transaction referred to in section 1320d–2(a)(1) of this title, means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1320d–1 through 1320d–3 of this title.

[1] So in original. Probably should be ''Part''.

(8) Standard setting organization

The term ''standard setting organization'' means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

(9) Operating rules

The term ''operating rules'' means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

(Aug. 14, 1935, ch. 531, title XI, § 1171, as added Pub. L. 104–191, title II, § 262(a), Aug. 21, 1996, 110 Stat. 2021; amended Pub. L. 107–105, § 4, Dec. 27, 2001, 115 Stat. 1007; Pub. L. 111–5, div. A, title XIII, § 13102, Feb. 17, 2009, 123 Stat. 242; Pub. L. 111–148, title I, § 1104(b)(1), Mar. 23, 2010, 124 Stat. 146.)

REFERENCES IN TEXT

The Indian Health Care Improvement Act, referred to in par. (5)(L), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, which is classified principally to chapter 18 (§ 1601 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

PRIOR PROVISIONS

A prior section 1171 of act Aug. 14, 1935, was classified to section 1320c–20 of this title prior to repeal by Pub. L. 97–35.

AMENDMENTS

2010—Par. (9). Pub. L. 111–148 added par. (9).

2009—Par. (5)(D). Pub. L. 111–5 substituted ''C, or D'' for ''or C''.

2001—Par. (5)(D). Pub. L. 107–105 substituted ''Parts A, B, or C'' for ''Part A or part B''.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title I, § 1105, Mar. 23, 2010, 124 Stat. 154, provided that: ''This subtitle [subtitle B (§§ 1101–1105) of title I of Pub. L. 111–148, enacting subchapter I of chapter 157 of this title, amending this section and sections 1320d–2 and 1395y of this title, enacting provisions set out as a note under section 1320d–2 of this title, and amending provisions set out as a note under this section] shall take effect on the date of enactment of this Act [Mar. 23, 2010].''

PURPOSE

Pub. L. 104–191, title II, § 261, Aug. 21, 1996, 110 Stat. 2021, as amended by Pub. L. 111–148, title I, § 1104(a), Mar. 23, 2010, 124 Stat. 146, provided that: ''It is the purpose of this subtitle [subtitle F (§§ 261–264) of title II of Pub. L. 104–191, enacting this part, amending sections 242k and 1395cc of this title, and enacting provisions set out as a note under section 1320d–2 of this title] to improve the Medicare program under title XVIII of the Social Security Act [subchapter XVIII of this chapter], the medicaid program under title XIX of such Act [subchapter XIX of this chapter], and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information and to reduce the clerical burden on patients, health care providers, and health plans.''

§ 1320d–1. General requirements for adoption of standards

(a) Applicability

Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1320d–2(a)(1) of this title.

(b) Reduction of costs

Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) Role of standard setting organizations

(1) In general

Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules

(A) Different standards

The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5.

(B) No standard by standard setting organization

If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part—

(i) paragraph (1) shall not apply; and

(ii) subsection (f) of this section shall apply.

(3) Consultation requirement

(A) In general

A standard may not be adopted under this part unless—

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f) of this section, consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations described

The organizations referred to in subparagraph (A) are the following: